

Food and Drug Administration, HHS

§ 299.4

upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by codeine alone.

EFFECTIVE DATE NOTE: At 67 FR 4907, Feb. 1, 2002, §290.2 was added; effective Apr. 2, 2002.

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a “controlled substance” in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.” This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are “blind.”

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, §290.5, promulgated under section 503(b) of the Federal Food, Drug, and Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.” The Spanish version of this is: “Precaucion: La ley Federal prohíbe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada.”

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term *emergency situation* means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a

controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

Subpart A—General Provisions

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299.3 Definitions and interpretations.

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299.5 Drugs; compendial name.

AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

SOURCE: 40 FR 14041, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 299.3 Definitions and interpretations.

(a) As used in this part 299, *act* means the Federal Food, Drug, and Cosmetic Act, sections 201–902, 52 Stat. 1040 (21 U.S.C. 321–392), with all amendments thereto.

(b) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part 299.

(c) The term *official name* means, with respect to a drug or ingredient thereof, the name designated in this part 299 under section 508 of the act as the official name.

§ 299.4 Established names for drugs.

(a) Section 508 of the Federal Food, Drug, and Cosmetic Act (added by the Kefauver-Harris Drug Amendments of 1962; Pub. L. 87–781) authorizes the Commissioner of Food and Drugs to designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Section 502(e) of the act (as amended by said Drug Amendments) prescribes that the